IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Wave 4 Cases Listed on Exhibit A to Plaintiffs' Motion*	

REPLY MEMORANDUM IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF TED ROTH, M.D.

In further support of their motion to exclude certain opinions and testimony of Defendants' urogynecology expert, Ted Roth, M.D., ("Dr. Roth"), Plaintiffs state as follows.

ARGUMENT

I. Dr. Roth failed to apply any objective, reliable standard in offering his warning opinions, and the foundation of his opinions is based on speculation into the minds of other pelvic floor surgeons.

Plaintiff does not take issue with Dr. Roth's credentials. Rather, Plaintiffs' claim is that Dr. Roth opinions are entirely subjective, without reference to any objective source or standard. The opposition brief fails to identify any standard or methodology applied by Dr. Roth, or any standard by which Dr. Roth's opinions regarding product warnings can be objectively evaluated. That gap is fatal to Dr. Roth's warnings opinions. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014), this Court precluded an expert's warnings opinions because the expert applied no standard at all to support his opinions, concluding: "Dr. Slack's subjective and conclusory approach is evidence that his opinion is based on mere speculation and personal belief." *Id.* at *32. The same applies to Dr. Roth, who has conducted no scientifically

reliable inquiry into what physicians actually knew about the risk of the pelvic mesh devices and applied no reliable standard to conclude Ethicon's warnings are adequate.

Ethicon does not contest Plaintiffs' argument that Dr. Roth is unqualified to apply the FDA Blue Book memorandum standard or the Code of Federal Regulations as the basis for his warning opinions. (Def. Mem. in Opp. at 7-8). Defendants have conceded that "Dr. Roth does not propose to testify about regulatory standards." (*Id.* at 4). The problem is, Ethicon identifies no objective standard that Dr. Roth **does** rely upon for his opinions that Ethicon's risk information is adequate. The Defendants' position is that Dr. Roth should be permitted to testify of the risks inherent to all surgeries to treat SUI and POP, and that all of those risks are commonly known to pelvic surgeons. *Id*. at 4.

Plaintiffs do not challenge Dr. Roth's ability to testify as to the risks of SUI surgery. The problem arises when Dr. Roth speculates as to the knowledge of **other physicians** in opining that **all** of those risks are commonly known to pelvic floor surgeons. He has done no scientifically reliable analysis to determine whether this is actually true. Ethicon cites *Winebarger v. Boston Scientific Corp*., No. 2:13-cv-28892, 2015 WL 1887222 at *15 (S.D. W. Va. Apr. 24, 2015) in support of its argument that Dr. Roth should be allowed to offer his warnings opinions in this case. However, in *Winebarger*, the Court simply ruled that Dr. Schull was qualified to testify as the risks he perceives to patients, and also offer the opinion that the Uphold DFU did not adequately convey those risks. *Id*. At no time Dr. Schull attempt to get into the minds of other physicians. He offered no opinions as to whether all physicians knew about the Uphold's risks, which is precisely what Ethicon would have Dr. Roth do here.

In addition, because Ethicon has offered no objective standard that Dr. Roth applied to opine that the warnings provided by Ethicon were adequate, this opinion should be excluded.

Defendants have conceded Dr. Roth will not testify about regulatory matters, meaning he is not applying the Code of Federal Regulations or Blue Book standard cited in his report. (*See* Mem. in Opp. at 4; Roth Report, Dkt. No. 3668-3, at 31). Ethicon now seeks to substitute Dr. Roth's review of the medical literature as the basis for his opinions that all of the risks inherent to SUI and POP surgeries are commonly known to experienced pelvic floor surgeons. However, this approach contradicts the standard he stated he applied in his expert report. (*See*, Ex. C, *supra*). And, the medical literature can only reveal risks that the authors knew—not the risks that all pelvic floor surgeons would know. Dr. Roth admitted that he has not studied the risks known by all surgeons, and thus his opinion on this issue is complete speculation. (*See* Roth Dep. re: Prolift +M, Dkt. No. 3668-4, at 59:10-21). Moreover, Plaintiffs cannot even ascertain which medical literature Dr. Roth is relying on, as Dr. Roth testified that he did not give final approval to his reliance list prior to it being served. (Roth Dep. re: TVT/TVT-O, Dkt. No. 3668-5, at 46:2-9).

Dr. Roth's foundationless opinion attempts to convey that the risks of SUI or POP surgeries are well known to pelvic floor surgeons, and thus the warnings provided by Ethicon were in fact, adequate. This transparent effort to justify the expert's deficient methodology should not be allowed, as it asks the Court to allow Dr. Roth to offer opinions regarding the adequacy of the pelvic mesh IFUs without applying any objective standard and without any foundation for the opinion, other than his speculative personal beliefs about what he thinks other doctors already know. Dr. Roth has performed no reliable or verifiable study or analysis as to what surgeons did or did not know, which is necessary in order to support a valid opinion that a warning was not necessary on any particular issue.

Thus, the only reliable testimony that Dr. Roth can offer relates to the risks of SUI or POP as seen with his patients. Where Dr. Roth's testimony becomes unreliable is when he makes the leap to assume that all physicians have read the same literature he has, and have fully understood and retained the contents, without any reliable methodology in arriving at these conclusions. For the opinion that the risks were well known to pelvic floor surgeons, we simply have Dr. Roth's say so, which is insufficient under *Daubert*. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) (stating that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

Dr. Roth's speculative, unsupported opinions regarding the knowledge of the medical community should not be permitted under *Daubert.* Moreover, allowing such opinions should be excluded under Rule 403. The natural conclusion the jury would draw from this testimony is that the warning provided by defendants' was adequate, despite the expert having no foundation and applying no objective standard for that conclusion. Thus, Dr. Roth's warning opinions should be excluded.

II. Dr. Roth is admittedly not an expert with regard to design, and his opinion that the design of polypropylene mesh is suitable for SUI or POP, and his opinions regarding the design of other meshes, should be precluded.

Dr. Roth is admittedly not an expert in design, and his only design opinion addresses whether polypropylene and other meshes are suitable for the treatment of POP or SUI, including the appropriateness of other meshes such as Vypro, Ultrapro, and PVDF/Dynamesh. (Def Mem. at 8). Dr. Roth's literature review does not qualify him to offer opinions regarding the design of the mesh, as it relates to selecting the appropriate mesh for a SUI or POP device, particularly

where he has admitted a lack of expertise in that area. Dr. Roth has already indicated a lack of expertise in the area of mesh design and materials:

> Q. Would you agree that you're not a biomedical engineer?
>
> A. I'm not.
>
> Q. Would you agree that you've never done any bench research on polypropylene mesh?
>
> A. I have not.
>
> Q. Would you agree that you've not done any bench research on polypropylene mesh?
>
> A. I have not

(Dkt. No. 3668-5 at 51:16-24).

In addition to his admitted lack of expertise, Dr. Roth cherry-picks information and testing for his mesh design opinions, ignoring contrary testing and data. He disregards Ethicon's own IFU and with regard to polypropylene mesh shrinkage:

> Q. So just to be clear, you do not believe that mesh contracture occurs with the Prolift +M?
>
> A. Correct.
>
> Q. Can I have you look at the Prolift +M IFU that is marked as an exhibit in front of you, and specifically I want to have you look at the adverse reaction section on page number two. And if you look under adverse reactions, the first bullet point one of the adverse reactions listed is contracture. Do you see that?
>
> A. I'm sorry under adverse reactions?
>
> Q. Yes, it's the last line of the first bullet point, fistula formation, contracture, scarring, mesh exposure, erosion or extrusion?
>
> A. Mm-hmmm.

(Mem, Ex. D at 54:2-17).

This Court has previously recognized the importance of an expert's admission that he is not an expert. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Roth, who admitted on multiple occasions during his recent deposition that he is not an expert on design. In addition, he has selectively cherry-picked data, making his methodology for reaching his opinions unreliable. *Barber v. United Airlines Inc.*, 17 Fed. App'x 433, 437 (7th Cir. 2001) (holding that a "selective use of the facts fails to satisfy the scientific method and *Daubert*").

Ethicon claims that Dr. Roth is not offering an opinion about the process of designing a product; rather, he is offering an opinion about whether polypropylene or other materials are suitable for the treatment of SUI or POP. (Def. Mem. in Opp. at 8). What Ethicon fails to realize is that selection of the proper (suitable) materials to make a product is part of the process of designing a product. *See Jolly v. General Motors Corp.*, 285 S.E. 2d 301 (N.C. App. 1982); *Cockerham v. Ward*, 262 S.E. 2d 651 (N.C. App. 1980). As such, Dr. Roth should be precluded from giving any opinions related to design of the subject products, including offering opinions that the design of polypropylene meshes are suitable for the treatment of SUI or POP, or addressing the suitability of the design of alternate meshes such as Vypro, Ultrapro, and PVDF.

III. Dr. Roth's opinions on the safety and efficacy of the mesh products should be excluded as he is not qualified, and he has applied a flawed, unreliable methodology.

Dr. Roth is admittedly not an expert in design, and Defendants appear to concede that he is not offering any opinions on design, but rather is offering opinions regarding safety and efficacy. (Mem. in Opp. at 8). By offering an opinion that the pelvic mesh products are safe and effective, Dr. Roth is, in effect, stating that the design of these products is safe and effective. Dr. Roth's use of mesh products, and his qualifications as a board-certified urogynecologist do not,

by themselves, uniquely qualify him to opine regarding the safety and efficacy of a medical device—any more than a licensed driver is qualified to opine about the safety of a vehicle based on how it feels when he drives it and based on what she has observed when others drive it. Defendants claim that the foundation of Dr. Roth's design opinions (which they characterize as safety and efficacy opinions) is his clinical, surgical, research, and teaching experience as well as his analysis of the peer-reviewed and scientific literature. (Def. Mem. at 11). A review of the literature does not provide sufficient basis for Dr. Roth to offer a reliable design opinion unless he can identify an appropriate standard that he applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

Here, in addition to admitting not being an expert in design, Dr. Roth has admitted he can articulate no objective standard for his opinions that the mesh devices are safe and effective:

> Q. So you would agree with me that a device like the TVT or TVT-O could have a high enough rate of vaginal or urethral erosion to where you would conclude that it was unsafe for the treatment of stress urinary incontinence?
>
> A. Again, that's a hypothetical question, because TVT and TVT-O don't have very high erosion rates or exposure rates at all. I mean, you know one of the reasons why I don't offer Burch procedures to most of my patients is because there is significant morbidity with a Burch. **So I guess I would agree that there is some threshold for, you know, safety. I don't know what that threshold, you know, would be for TVT, TVT-O**……

(Dkt. No. 3668-5 at 191:4-20). Dr. Roth also testified that he was unsure if a combined 19% vaginal and urethral erosion rate would be high enough to conclude that a TVT or TVT-O was not safe, stating, "You know, I don't know that number. I can't – I can't give you a number that

would sway me from doing the procedure." (*Id*. at 192:10-193:12). According to Dr. Roth's analysis, there is no objective standard to declare a mesh device to be unsafe. Nowhere does Dr. Roth or Ethicon identify any objective standard applied by Dr. Roth, or by which Dr. Roth's opinions on safety and efficacy can be tested or objectively evaluated. As such, he should be precluded from giving any opinions related to the safety and efficacy of the mesh products.

IV. Dr. Roth should be precluded from offering precise statistics regarding his own personal experiences with the mesh.

Ethicon appears to concede that Dr. Roth will not be offering an opinion that his own patients implanted with the Prolift +M device have between an 8 and 15 percent exposure rate, as it is not disclosed in his expert report. (Mem. in Opp. at 13). However, Ethicon states that Dr. Roth will opine that there is really no difference between his patients implanted with mechanically cut and laser cut mesh slings. (*Id*. at 14). This opinion suffers from the same fatal flaws as his testimony regarding his personal exposure rate with Prolift +M, as it is essentially offering an opinion that there is no statistically significant difference in safety or efficacy between his patients treated with laser cut mesh or mechanically cut mesh. This is exactly the kind of precise statistics based on unreliable, undisclosed data that this court has excluded in the past. *See In re Ethicon*, 2016 WL 4542054 (S.D. W. Va. 2016). Dr. Roth as admitted that this retrospective chart review of laser cut vs. mechanically cut patients consisted of randomly pulling some charts; he cannot state the exact number of charts; he just "sort of looked through their records"; he can't state with certainty the average length of follow-up; he does not know what percentage of patients had been lost to follow up; there was no written analysis or findings; and that "**it wasn't a very rigorous analysis.**" (Dkt. No. 3668-5 at 23:11-26:3). Therefore, this court should exclude Dr. Roth from testifying as to his personal experiences with the mesh products in this case.

CONCLUSION

For the reasons stated above and in prior briefing, Plaintiffs respectfully request that this Court grant Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Ted Roth, M.D.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Thomas P. Cartmell